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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,696	06/19/2001	Lisle W. George	481.06	4037

22798 7590 05/11/2005

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT PAPER NUMBER

1645

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,696

Applicant(s)

GEORGE ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 12-14 and 34-56 is/are pending in the application.
4a) Of the above claim(s) 1-4, 6, 12, 34-48 and 51-54 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 13, 14, 49, 50, 55 and 56 is/are rejected.
7) ☒ Claim(s) 13 and 14 is/are objected to.
8) ☒ Claim(s) 1-4, 6, 12-14 and 34-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

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DETAILED ACTION

New claims 34-56 have been submitted.

Claims 1-4, 6, 12-14 have been amended

Claims 1-4, 6, 12-14, and 34-56 are pending

Claims 5, 7-11, and 16-33 were canceled in the Amendment of April 16, 2003.

Claim 15 was canceled in the amendment dated March 29, 2004.

Claims 1-4, 6, 12, 34-48 and 51-54 stand withdrawn from consideration in so far as the claims read on a cell that recombinantly expresses the cytotoxin; claim 34 has been amended to depend from claim 2 which is directed to a cell that expresses cytotoxin.

Claims 13-14, 49-50, 55-56 are under consideration, in so far as they are directed to isolated peptides, polypeptides or proteins of SEQ ID NO 2, and not cells that comprise SEQ ID NO 2 or variants thereof.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

2. Newly amended and submitted claims 1-4, 6, 12, 34-48, 51-54 stand withdrawn as they are directed to a cell that recombinantly expresses cytotoxin. Claims 34-48 now depend from claim 2 which is directed to an invention that is independent or distinct from the invention originally claimed and examined. For the following reasons these claims are being withdrawn from consideration as being directed to a non-elected invention (election by original presentation):

The amended and new claims are directed to: a Cell that expresses a recombinant DNA sequence of SEQ ID NO 1 or a fragment or a modified variant, wherein the variant is specifically bound by an antibody. The embodiment would have been grouped with of original Group II, classified in class 536, subclass 23.1 and not with Group I, which was examined in the First Action on the merits, in paper number 10, dated November 12, 2002.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

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on the merits, accordingly, claims 1-4,6,12, 34-48 and 51-54 are herein withdrawn from consideration.

Claim 2 depends from claim 1 and has been amended to be directed to a cell. New claim 34 is dependent from claim 2. Claim 34 is directed to “An anti-Moraxella bovis vaccine” that consists essentially of “a cytotoxin or cytotoxin fragment provided in claim 2. As claim 2 is directed to a cell that comprises a recombinant nucleic acid that expresses the cytotoxin or cytotoxin fragment of claim 1, claim 34 is directed to a cell that provides the cytotoxin through expression of the cytotoxin or cytotoxin fragment of claim 1. Claim 2 is directed to a combination composition defined to be a cell expressing a cytotoxin or cytotoxin fragment, wherein the cytotoxin or cytotoxin fragment are expressed in such a way that they can be “obtained (future tense process limitation recited in claim 2)” in a purified form at some future point in time. Claim 34, and all claims (claims 35-48) dependent therefrom are being read as compositions that are independent and distinct from the compositions originally examined and are being withdrawn from consideration as being directed to a non-elected invention. Claim 34 recites a process limitation “provided in claim 2”. The cytotoxin or cytotoxin fragment is provided in claim 2 when the recombinant cell expresses of the recombinant nucleic acid. Claims 34-48 stand withdrawn from consideration as being directed to a non-elected invention, as the compositions of claims 1 and 2 are directed to “a recombinant nucleic acid molecule” or “a modified variant thereof” which are expressed in the cell, and Applicant’s elected invention was directed to Group I, peptides, polypeptides or cytotoxin protein containing compositions of SEQ 2 (product by process claim limitations to produce SEQ ID No 2) or SEQ Id NO 6 or 13. See 37 CFR 1.142(b) and MPEP § 821.03.

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Rejections Withdrawn

3. All claims rejected or objected to that have been canceled or amended to recite a non-elected invention are herein withdrawn.

New Claims/New Claim Limitations/New Grounds of Rejection

Claim Objections

1. Amended claims 13-14 are objected to because of the following informalities: Claims 13 and 14 have been amended to recite "An isolated amino acid sequence", the relationship of the amino acids should be defined by a peptide, polypeptide or protein structure; this objection could be obviated by amending the claims to recite ---An isolated peptide consisting of the amino acid sequence of SEQ Id NO 6 or 13---- (or an equivalent phrase for which the instant Specification provides original descriptive support). Appropriate correction is required.

Double Patenting

2. Claims 49-50 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 13-14. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 55-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Claim 55 subparagraph e) recites the phrase "the fragment of (a) comprising any combination of (b), (c) or (d)." Original descriptive support for a genus of polypeptides that comprise any combination of fragments put together in any order could not be found in the instant Specification. Therefore, claims 55(e) and claim 56 (e) which depends from claim 55(e) recite New Matter.

6. Claims 55-56, subparagraphs f-h are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: The claims recite a range of amino acids, but no reference SEQ ID NO. While the preamble of the claim recites SEQ ID NO 2, reference to this identifier would structurally identify the recited ranges of amino acids to refer back to SEQ ID NO 2.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. New claims 55 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Gray et al (Vet. Microbiol., Vol. 43, pages 183-196, 1995, cited in Applicant's Specification at page 16, paragraph 2).

Gray et al disclose the instantly claimed invention directed to:

(Instant claim 55 (a) and 56) a composition that comprises a fragment (the immunoblot showed immunoreactivity with the 110 kDa protein as well as several lower molecular weight bands, which would be fragments of the larger protein cytotoxin see page 190, paragraph 2, and Figure 2 and 3; also see page 194, paragraph 3 "use of the monoclonal antibodies may be attributed to recognition of smaller size antigenically related peptides") of Moraxella bovis cytotoxin (see title) that is capable of stimulating antibody (rabbit serum, polyclonal antibodies) production (see section 3.2 Immunoblot analysis) and the antibodies specifically (monoclonal antibodies and rabbit serum (polyclonal antibodies) immunoreacted with not only the 110 kDa protein but with two additional lower molecular weight bands, page 190-191), and therefore would inherently bind to fragment of the polypeptide of SEQ ID NO 2.

Prior art Made of Record and not relied upon:

****Potter et al (US Pat. 5,594,107) in light of PG Pub 20030118566 A1 [0182]: Potter et al disclose the instantly claimed invention directed to a fragment of an RTX cytotoxin of Moraxella bovis (see Potter et al, col. 5, line 7), wherein the fragment is an amino acid sequence of SEQ ID NO 2 (see col. 5, lines 1-2), specifically Gly-Gly-X-Gly-Asn-Asp (Potter et al SEQ ID NO 5) which are amino acids 729-734 of Instant SEQ Id NO 2.

***** PG Pub 20030118566 A1 [0182] who shows anti-glycine antibodies are commercially available thus defining the Glycine in the disclosed fragment of Potter et al to be immunogenic and would specifically immunoreact with an antibody thereto.

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Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
April 27, 2005

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